

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ACH63183WO00		FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/GB2004/003329		International filing date (day/month/year) 30.07.2004	Priority date (day/month/year) 30.07.2003	
International Patent Classification (IPC) or national classification and IPC A61K9/107, A61K9/12, A61K9/48				
Applicant DISPERSE LIMITED				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 13.05.2005		Date of completion of this report 13.07.2005		
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Boulois, D Telephone No. +31 70 340-3878		



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/003329

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-26 as originally filed

Claims, Numbers

1-22 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/003329

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	5-8, 10, 11, 18-20
	No: Claims	1-4, 9, 12-17, 21, 22
Inventive step (IS)	Yes: Claims	5-8, 10, 11, 18-20
	No: Claims	1-4, 9, 12-17, 21, 22
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following documents:

D1: US-A-4 999 198 (BARNETT ET AL) 12 March 1991 (1991-03-12)

D2: WO 97/32559 A (DISPERSE TECHNOLOGIES LIMITED; WHEELER, DEREK,
ALFRED) 12 September 1997 (1997-09-12)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-4, 9, 12-17, 21, 22 is not new in the sense of Article 33(2) PCT.

The document D1 discloses the preparation of drug delivery systems in polyaphrons form (see D1, col. 2, l. 23-46). The drug used in D1 is scopolamine. The description of the present application discloses on pages 9-13 a list of drugs presented as "poorly water soluble drugs". A great proportion of these are in fact water soluble (for instance all salts). Scopolamine has therefore to be considered also as poorly water soluble drug.

The hydrophilic phase disclosed in D1 is clearly comprised between 1 and 20% by weight, since col. 2 lines 23-42 discloses the presence of 5 ml of a hydrophilic phase, which is the foam.

Consequently, the subject-matter of claims 1-4, 9, 12-17, 21, 22 is not new over D1 (Article 33(2) PCT).

3. The documents D1 and D2 appear to be of particular relevance as far as inventive step is concerned (Article 33(3) PCT). These documents solve indeed the same problem, namely making compositions in form of biliquid foam, but for topical or transdermal forms. The problem of the present application being to make delivery forms adapted to oral delivery, the present application, as far as novel subject-matter is concerned, is considered to be inventive over D1 or D2 (Article 33(3) PCT).